

Dedicated to Safe Drinking Water

June 11, 2003

Water Docket
Environmental Protection Agency
EPA West, Room B102
1301 Constitution Ave. NW
Washington, DC 20460
Attn: Docket ID No. OW-2003-0013

06-11-03 P01:47 IN

Re: Planned Information Collection Request (ICR) for the Drinking Water Regulations Cost and Compliance Retrospective Survey

Dear Docket:

The American Water Works Association (AWWA) is pleased to offer its comments on the planned Information Collection Request (ICR) for the Drinking Water Regulations Compliance and Cost Retrospective Survey as published in the April 14<sup>th</sup> Federal Register (68 FR 17937). The AWWA is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 56,000 plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,700 utilities that supply roughly 80 percent of the nation's drinking water.

AWWA has commented extensively on the economic analyses that have supported each of the existing drinking water regulations. Volunteers, contractors, and staff have literally spent thousands of manhours (and several hundred thousand dollars) on data collection and analyses for comments on proposed drinking water regulations and the underlying economic analyses. Admittedly, EPA has responded to some of our recommendations in our comments, but we continue to have significant concerns with how EPA is conducting its economic analyses to support its drinking water regulations.

AWWA generally supports EPA's efforts to take a retrospective look at existing drinking water regulations. It is critical to validate the assumptions made in the economic analyses with actual compliance data. AWWA conducted a similar retrospective look at the uranium regulation that focused more on the process used to develop the benefit-cost analysis, rather than the underlying treatment costs. A copy of the report is enclosed.

EPA needs to be clear in its objective for this study. What questions are you trying to answer with this survey? Based on the information in the *Federal Register* notice, it appears that the objective is to develop as detailed understanding as possible about the decisions made for compliance (new treatment, treatment modifications, new water source) and the associated capital and operation and maintenance (O&M) costs for those decisions.

How the questions are asked in the survey will affect the answers given. The survey design and the actual survey questions will both be critical to ensure that the responses received are clear and unambiguous. AWWA would like to offer assistance to EPA in the designs of the screener survey, the design of the full survey, and in publicizing this survey effort and encouraging the impacted systems to fill out the survey.

If you have any questions about these comments, please feel free to call Alan Roberson or me at 202-628-8303.

Yours Sincerely,

Thomas W. Curtis

Deputy Executive Director

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### Enclosure

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### A REPORT CARD ON EPA'S COST-BENEFIT ANALYSIS FOR URANIUM, AND ITS USE IN SUPPORTING THE FINAL RULE

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### **EXECUTIVE SUMMARY**

The Maximum Contaminant Level (MCL) for uranium was finalized on December 7, 2000 (65 FR 76707). Key points regarding the uranium MCL and the cost-benefit analysis the Agency developed in support of the rulemaking are:

### 1. The uranium MCL establishes precedent in the use of cost-benefit analysis in standard setting.

- The uranium standard setting establishes important precedent in that it represents the first time EPA has explicitly used its discretionary authority to use a cost-benefit analysis (CBA) to establish an MCL.<sup>1</sup>
- Because this rulemaking is precedent-setting, it is important that the CBA be performed
  in accordance with best practices and consistently applied according to the intent of the
  governing statute. Unfortunately, the CBA and its interpretation by the Agency has
  several limitations.
- The report card on the CBA (Exhibit S.1) indicates several areas in which the Agency receives poor grades.

### 2. The unquantified health risks (potential kidney toxicity) are the basis for the MCL, but need to be addressed in a more systematic manner in the CBA.

- The health concern that serves as the principal basis for the rule is a reduced risk of potential kidney toxicity. This potential health benefit cannot be quantified in terms of estimated numbers of cases avoided because it is not known whether the potential for cellular-level changes within the kidney may be associated with an increased risk of an adverse health effect.
- Since the level of risk (if any) is unquantifiable, it is not possible to put a dollar value on the risk reduction benefits. However, there are meaningful semi-quantitative ways to assess these types of benefits within a CBA, as demonstrated in the "break even" analysis submitted with AWWA's comments on the Notice of Data Availability (NODA), issued in May 2000, and as updated here in Appendix C.

<sup>1.</sup> Under section 1412(b)(6) of the Safe Drinking Water Act Amendments of 1996, the Administrator can set an MCL at a level other than what is as close to the MCLG as technically feasible if the benefits at that level do not "justify" the costs.

## AWWA Report Card on EPA's Uranium Rulemaking

## AWWA Report Card on EPA's Uranium Rulemaking

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Occurrence	Treatment Costs	Monitoring Costs	Affordability	Human Health Benefits	Benefit-Cost Comparison	Consideration of Nonquantified Benefits
Occu	Treat	Mon	Affo	Ten E	Bene	Cons

Adherence to Guidelines and Directives D

### Exhibit S.1 (cont.)

### Occurrence

The Agency relies on interpolation between two unsatisfactory sets of occurrence estimates, and fails to address key technical issues raised in prior rulemakings and reiterated in public comments. The occurrence results are at odds with limited available field data, and underestimate the number of systems impacted, especially in the larger size categories.

### -- " Treatment Costs

EPA's estimated treatment costs are not transparent or replicable, and are based on an unreasonable assumption that 34% of systems will comply by tapping alternative, low cost water sources. EPA does not specify waste management technologies used in the cost analysis. EPA also omits the costs of compliance monitoring (which typically are included in cost-benefit comparisons).

## G+ Monitoring Costs

EPA significantly reduced its estimated monitoring costs between the NODA and final rule by changing the requirements — relying now on gross alpha measurements for systems with low gross alpha (\$\leq 15 \partial Ci/L)\$. Monitoring costs are excluded from the CBA, however, and are annualized in a manner that makes them inconsistent with the other components of annualized compliance costs.

### - Affordability

Dt. ... .....

The Agency relies only on the costs of promulgated rules in setting its baseline household water bill, and does not assess affordability in a simple sensitivity analysis that considers the impact of multiple proposed rules. EPA also relies solely on 2.5% of median household income as its measure of affordability, and should also show sensitivity to alternative threshold values (e.g., 2.0%), and also show water bills as a percent of income for households in poverty.

## Human Health Benefits

EPA quantifies and assigns a monetary value to cancer risk reductions, but fails to apply standard latency and discounting principles in its assessment. Accounting for latencies and discounting (and income growth effects) are the proper ways to conduct these analyses, and were endorsed by the Science Advisory Board. EPA needs to follow accepted best practices for benefits valuation.

# D Benefit-Cost Comparison

EPA avoids a failing grade by providing estimates of incremental benefits and costs. However, the Agency fails to show incremental net benefits for each relevant regulatory option, and also fails to make any effort to account for unquantified kidney toxicity benefits. Given that the Agency claims to use the CBA results as the basis for selecting an MCL at a level other than what is technically feasible, the incomplete benefit-cost comparison is especially problematic.

# F Consideration of Nonquantified Benefits

EPA claims it relied on the CBA to select the MCL, and that the primary health benefit of the standard is for kidney toxicity. However, the Agency failed to undertake any efforts to examine how the CBA results relate to renal toxicity concerns, even though it received public comments illustrating a useful approach for doing so.

# D Adherence to Guidelines and Directives

In several regards the Agency adheres to internal and external guidelines and directives. However, important deficiencies remain, such as failing to discount future benefits, using inconsistent bases for annualizing different cost components, and omitting monitoring costs and important unquantified benefits from the cost-benefit comparisons.

• The Agency uses its discretionary CBA authority in setting the standard, but at the same time, in its response to comments, the Agency claims it is irrelevant to apply useful CBA techniques for assessing the nonmonetary kidney toxicity benefits. This reveals a fundamental flaw in EPA's logic in this rulemaking — it uses its CBA authority to set the MCL, claiming that it "believes that 30 μg/L maximizes net benefits" (EPA response to comments 9.A.12). Yet at the same time, the Agency offers no CBA assessment of the MCL that considers the nonquantified benefits [and EPA claims that the demonstrated "break-even analysis is not relevant" (EPA response to comment 9.B.19)].

### 3. The cost estimates appear understated and are not supported by transparent explanations or readily available back-up documentation.

- EPA relies on questionable occurrence distributions, especially when determining its "Best Estimate" of affected systems.
- It is difficult to determine the basis for the cost estimates or reproduce them.
  - EPA's decision tree relies to an unreasonable extent on nontreatment options (34% of affected systems), which departs from other cost analyses. In addition, the treatment category "softening/iron treatment" is too broad to determine what technology(ies) EPA used in its cost analysis.
  - EPA provides cost curves for residuals management, but does not indicate what residuals management technologies were used in its cost estimates.
  - EPA outlines its aggregation method in general terms, but does not identify the actual model (e.g., was SafeWater Suite or SafeWaterXL used?).
- EPA does not include monitoring costs in its CBA for the final rule, but did properly include them in the NODA CBA. Monitoring costs may be a significant portion of the total costs of the rulemaking (e.g., in the NODA, monitoring costs ranged from 10% to over 50% of total costs, depending on the MCL option and occurrence estimation approach used). This share will be much less using compliance monitoring costs as revised under the final rule (i.e., less than 5% of total compliance costs for the selected MCL of 30 μg/L).
- If the costs are understated, then the cost-benefit rationale for the final MCL (30  $\mu$ g/L) becomes less defensible.

### CHAPTER 1 INTRODUCTION

### **OBJECTIVE**

This "report card" provides a brief review of the recent final EPA rulemaking for uranium, focusing on how well the Agency's supporting cost-benefit analyses (CBAs) — and EPA's policy interpretations of them — adhere to standard notions of best practices. The objective is to provide a basis for discussions on how EPA may need to modify how it develops and applies its CBAs in future rulemakings.

The regulation examined in this specific review is the recently promulgated radionuclides rule, and specifically the final uranium MCL, which was set at 30  $\mu$ g/L. This rulemaking was finalized on December 7, 2000 (65 FR 76707).

### **BACKGROUND**

In setting an MCL, important public health issues and sizable financial consequences often are at stake. Therefore, it is vital that EPA's drinking water regulations are based on sound science and adhere to the principles of good economic and public policy analysis.

Under statutory and executive mandates, EPA must develop cost-benefit analyses and other studies in conjunction with its rulemakings. These investigations by EPA address the science, engineering, and economic underpinnings of its rulemaking options. The intent is to have EPA develop human health risk assessments, technology and cost documents, and other studies to help ensure that its standards are based on sound science and provide a prudent balancing of benefits with costs. These EPA analyses are embedded in documents that are made publicly available when a rule is proposed or promulgated, or when a Notice of Data Availability (NODA) is issued. Such documents include Health Risk Reduction and Cost Analyses (HRRCAs), Economic Analyses (EAs, formerly known as Regulatory Impact Analyses, or RIAs), and Technology and Cost (T&C) Documents.

EPA must make these documents and other relevant materials (including full documentation) available for timely review by stakeholders and the interested public, as part of

the rulemaking docket. The public comments on these analyses often provide considerable insights and new information. For example, AWWA, among other organizations, typically submits detailed and relevant comments on many aspects of proposed rules, using the extensive expertise of its members, staff, and consultants. Public comments submitted on proposed rulemakings or NODAs must be addressed by the Agency as part of its development of a final rule.

Recent rulemaking activity in EPA's drinking water program has raised stakeholder concerns that standards are not always based on sound science, that the Agency's supporting analyses (RIAs, HRRCAs, etc.) are technically lacking or otherwise insufficient, and that they are lacking in appropriate transparency and documentation. There also is concern that recent EPA actions reveal that the Agency is not adhering to appropriate or best practices [including those articulated in Agency guidelines and Science Advisory Board (SAB) reports] for conducting or interpreting benefit-cost analyses in standard setting.

In addition, there is concern that EPA is not taking public comments into serious consideration when finalizing its rules. Some might argue that EPA's typical comment response document takes more of a "check-off" approach than a balanced consideration of the comments, merits, and implications. If this is the case, then the Agency may be overlooking key facts and valuable alternative perspectives when it revises its analyses and considers whether and how to alter the proposed standard into a final rule.

### KEY QUESTIONS AND EVALUATION CRITERIA

In the sections that follow, key aspects of EPA's recent uranium MCL rulemaking are evaluated. The questions of principal interest include the following:

- How closely do the final rule and its Economic Analysis address or reflect AWWA's submitted comments on the NODA?
- How well do the final rule and Economic Analysis meet the intent of the CBA provisions of the Safe Drinking Water Act (SDWA), as amended in 1996?
- How closely do the final rule and Economic Analysis follow the Agency's new CBA guidelines, as provided in *Guidelines for Preparing Economic Analyses* (dated September 2000)?

 To what extent do the rulemaking and Economic Analysis conform with other regulatory guidance and directives, including Executive Orders (EOs) and Circulars from the Office of Management and Budget (OMB)?

In addressing these key questions, the following evaluation criteria are applied:

- Do the analyses adhere to best practices, guidelines, and directives?
- Are the analyses transparent, consistent, and replicable?
- Do the data, methods, and results of the analyses appear to be accurate and credible?
- Are the results of the analyses properly interpreted within the policy-making and statutory context?
- Do the analyses and rulemaking appear to be reasonably responsive to public comment, technical reviews, and other stakeholder input?

### **OUTLINE OF REPORT**

The report addresses eight different topic areas. Each topic reflects a relevant component of the CBA that must be performed in accordance with the provisions of section 1412(b)(3)(C) of the SDWA Amendments of 1996. The issues addressed are:

- The occurrence analysis that underlies the cost and benefit analyses (Chapter 2)
- Treatment cost estimate development, especially for small systems (Chapter 3)
- Whether monitoring cost estimates are reasonable, and whether they are properly included in the CBA (Chapter 4)
- How the affordability analysis is performed with respect to cumulative regulatory impacts and the associated changes in baseline household water bills (Chapter 5)
- How latency and discounting issues are addressed in valuing the benefits of reduced cancer mortality risks (Chapter 6)
- How benefits are compared to costs, particularly in terms of whether incremental analyses are adequately developed and used (Chapter 7)

- How nonquantified benefits (potential kidney toxicity risks) are addressed and interpreted within the CBA (Chapter 8)
- The degree to which the CBA adheres to EPA's "Guidelines," other applicable federal directives and guidance, and general notions of best practices (Chapter 9).

### CHAPTER 2 OCCURRENCE ANALYSIS

### **ISSUE**

Occurrence analyses are the foundation for both benefit and cost analyses — estimating the number of community water systems that may exceed a given MCL option. This chapter examines the selection and interpretation of the two occurrence distributions EPA developed. Also examined is how the Agency interpolated between occurrence estimates for 20  $\mu$ g/L and 40  $\mu$ g/L to predict the number of systems above the final MCL of 30  $\mu$ g/L.

### **EPA'S APPROACH AND FINDINGS (FINAL RULE)**

In the final rule, EPA used two occurrence analyses for uranium based on the NRIS data for groundwater systems. One approach used a directly proportional method of extrapolating the data and the other used a lognormal interpretation of the NIRS data. In both cases, EPA split the NIRS data into two size categories: 25 to 500 people served and 501 to 1 million people served. For surface water systems, EPA assumed that that the occurrence values are one-third the values of those for the groundwater distributions. EPA analyzed systems serving over 1 million people individually.

EPA used these distributions to define low and high estimates for uranium occurrence, and states that the Agency's "best estimate" of occurrence is the average of the two distributions. Exhibit 2.1 summarizes these estimates.

EPA states that the number of affected systems at MCL options of 20  $\mu$ g/L, 40  $\mu$ g/L, and 80  $\mu$ g/L is 900, 360, and 110, respectively. Exhibit 2.1 also includes the annual compliance costs for the direct proportional and log normal models, and its "best estimate" for these three MCL options. By inspection, one can easily see that the annual compliance costs are dramatically affected by the occurrence assumptions for these three MCL options.

Exhibit 2.1 EPA's estimates of systems exceeding uranium MCL options

Direct proportional		Log	normal	"Best estimate"		
MCL option	Systems	Annual cost (\$M/yr)	Systems	Annual cost (\$M/yr)	Systems	Annual cost (\$M/yr)
MCL =20 μg/L	830	25.5	970	155.4	900	90.4
$MCL = 30 \mu g/L^a$	400	6.3	600	93.1	500	49.7
$MCL = 40 \mu g/L$	300	2.2	430	64.3	360	33.3
$MCL = 80 \mu g/L$	40	0.2	170	25.5	110	12.9

a. Interpolated values.

Note: Number of systems based on Exhibit 7-2 of EPA's Economic Analysis and annual cost from Exhibit 6-7 of EPA's Economic Analysis.

Exhibit 2.1 also summarizes EPA's estimates for 30  $\mu$ g/L, which was adopted as the MCL. However, rather than perform a new CBA for a 30  $\mu$ g/L MCL, the Agency used interpolation to first compute the number of affected systems and then the associated costs, population affected, risk reduction, and benefits. The Agency fit the data with power functions to describe a relationship between MCL option and the parameter of interest (e.g., number of affected systems). EPA illustrated the relationship for number of systems in Exhibit 7-1 of the Economic Analysis.

### **EVOLUTION OF EPA'S APPROACH**

Comparison to the NODA approach. The two occurrence distributions used in the final rule were unchanged from the two distributions developed for the NODA. The key difference is that for the final rule, EPA indicates that the two distributions bracket the actual occurrence, that the "best estimate" is the average of the two distributions, and that EPA has used interpolation methodology for the 30  $\mu$ g/L MCL rather than redo the analysis for that case.

Key comments on the NODA approach. Comments submitted on the NODA (e.g., Comment No. 19.A.1) suggested that the NIRS occurrence data seem to resemble more of a Weibull distribution (i.e., exponential) rather than a log normal distribution and recommended that the Agency, at a minimum, should perform a statistical test of the log normal distribution. In addition, the Agency's extrapolation of the groundwater data to surface water occurrence, assumes that concentrations in surface water are one-third those observed in groundwater. A

further comment was that EPA should consider other factors, such as geological conditions, that could explain uranium occurrence, rather than relying solely on system size. The use of grouped data by geologic provinces was suggested to develop more robust occurrence estimates.

Degree to which the approach in the final rule reflects public comments. EPA indicates that the Agency had investigated the use of a Weibull and other distributions to analyze the NIRS data and found that the log normal model fit the data as well as any other. EPA refers the reader to the radon Regulatory Impact Analysis for details, but initial inspection of that document indicates that alternative statistical models for occurrence are not discussed. EPA indicated that it could not use the NIRS data for analysis by geological provinces because a much larger sample size would be required and indicates that was not the purpose of the NIRS study. However, EPA did not consider pooling its NIRS data across system sizes in order to enlarge the sample size, nor does it consider how uranium-specific interpretation of the NIRS data may differ from other contaminants in NIRS.

### **EVALUATION AND RELIABILITY OF THE EPA RESULTS**

EPA has continued use of the direct proportional and log normal models, using an average of the two models as its "best estimates." The direct proportional method appears to be inappropriate for groundwater systems, because it indicates no occurrence for systems serving greater than 500 people for the 40  $\mu$ g/L and 80  $\mu$ g/L MCL options. However, there are data from larger water utilities in California and other states (e.g., in Nebraska) that indicate uranium levels above 40  $\mu$ g/L in their groundwater. Occurrence issues are discussed further the Appendix A.

As a comparison to EPA's estimates of affected systems at the 30  $\mu$ g/L MCL, Exhibit 2.2 was prepared to show how the interpolation could be done for groundwater systems by population served category. This analysis indicates slightly higher numbers than those predicted by EPA.

Exhibit 2.3 presents a similar analysis for surface water systems. Again, the analysis indicates a slightly higher number of systems than those predicted by EPA.

Exhibit 2.2 Occurrence distributions for groundwater systems

	Number of affected CWS							
	20 μg/	20 μg/L MCL		30 μg/L MCL <sup>a</sup> 40 μg/L MCL		/L MCL	80 μg/L MCL	
Population served category	DP	LN	DP	LN	DP	LN	DP	LN
25-100	369	324	256	217	144	146	21	60
101-500	391	342	272	230	152	155	22	64
501-1,000	20	83	10	54	0	35	0	13
1,001-3,300	24	101	12	65	0	42	0	16
3,301-10,000	11	44	0	29	.0	19	0	7
10,001-50,000	5	23	0	15	0	10	0	4
50,001-100,000	1	2	0	1.4	0	1	0	< 0.5
100,000-1,000,000	00.5	1	0	1	0	1	0	< 0.5
Totals	821	921	550	625	296	408	42	165

DP = directly proportional

LN = log normal

a. Values for 30  $\mu$ g/L are estimated for this analysis. For DP, based on arithmetic mean, and for LN, based on geometric mean, of results for 20  $\mu$ g/L and 40  $\mu$ g/L.

Exhibit 2.3 Occurrence distributions for surface water systems

	Number of affected CWS							
	20 μg/L	MCL	30 μg/L	MCL <sup>a</sup>	40 μg/L	MCL	80 μg/L	MCL
Population served category	DP	LN	DP	LN	DP	LN	DP	LN
25-100	1	6	0	3	0	2	0	1
101-500	3	12	0	8	0	5		
501-1,000	0	5	0	3	0	2		
1,001-3,300	0	10	0	6	0	4	0	1
3,301-10,000	0	8	0	5	0	3	0	1
10,001-50,000	0	7	0	4	0	2	0	1
50,001-100,000	0	1	0	· <1	0	< 0.5	. 0	< 0.5
100,000-1,000,000	0	1	0	<1	0	< 0.5		0.5
Totals	4	50	0	30	10	19		

DP = directly proportional

LN = log normal

a. Values for 30  $\mu$ g/L estimated for this analysis. For DP, based on arithmetic mean, and for LN, based on geometric mean, of results for 20  $\mu$ g/L and 40  $\mu$ g/L.

Adherence to best practices, guidance, and directives. EPA's occurrence efforts for uranium are very limited compared with efforts taken for other recent rules (e.g., the 1999 radon proposal and the 2001 arsenic rule). EPA did perform an analysis of uranium occurrence in NTNCS that examined the likelihood of higher uranium levels in various states, based on the same Oak Ridge study used to compare CWS groundwater and surface water ratios. In addition, the Agency obtained occurrence data from seven states, including California, but apparently did not use this information except to do a "what if" analysis of how subtracting California occurrence/noncomplying systems from the analysis, would affect compliance costs for the 40 μg/L option.

Transparency and replicability. EPA's analysis is generally transparent and can be replicated. However, an exponential equation better fits the direct proportional occurrence data for number of affected systems than the power equation EPA used (see Appendix A). The main effect of this difference is that the number of affected systems for the 30 μg/L MCL would be 500 rather than 400 for the direct proportional distribution, or 550 versus 500 affected systems for EPA's best estimate. This is also closer to the estimates shown in Exhibits 2.2 and 2.3. It is also closer to the 558 affected systems that EPA used in its Information Collection Request for Radionuclides analysis (see Chapter 4).

### **EPA'S INTERPRETATION OF RESULTS**

EPA has acknowledged that its two occurrence models have limitations, but believes it has made the best use of the information it had available.

### OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D. EPA has not made convincing arguments that actual occurrence of uranium in groundwater systems is bounded by its directly proportional and log normal distributions. This is especially true for groundwater systems serving populations above 500. The averaging method may be more appropriate for surface water systems, where occurrence is poorly understood. The Agency has not undertaken the effort to resolve these issues that it has with other recent rule makings.

### **CHAPTER 3**

### TREATMENT COST ESTIMATES (FOR THE 25-500 PERSONS SERVED CATEGORIES)

### **ISSUE**

Treatment costs are important in determining the financial impacts on water utilities of complying with a new MCL. Many of the impacted CWS are very small systems, with populations served between 25 and 500 people. EPA treatment cost estimates changed appreciably for the 25 to 100 and the 101 to 500 persons served size categories between the NODA analyses and the final rule. In this chapter, we examine the EPA documents to determine if the justification for the change is explained and supported.

### **EPA'S APPROACH AND FINDINGS (FINAL RULE)**

Approach. In support of the final rule, EPA's Economic Analysis (U.S. EPA, 2000e) provided cost estimates for uranium MCL options of 20 μg/L, 40 μg/L, and 80 μg/L by population categories for affected groundwater and surface water sources. These estimates provided annualized capital costs, annual operations and maintenance (O&M) costs, and total annual costs (sum of the other two components). Separate cost estimates were developed for the direct proportional occurrence distribution and the log normal occurrence distribution by system size categories.

Findings. EPA estimated that most of the affected systems are in the two smallest population categories, serving 25 to 100 people and 101 to 500 people, and that these system would bear the major economic impact of setting a uranium MCL. Exhibit 3.1 compares the total annual costs for very small systems in these two categories estimated in the NODA and the final rule. The total annual costs decreased significantly between the NODA and the final rule. Specifically, the costs decreased by \$900,000/year (11%) for the 20  $\mu$ g/L option, about \$1.8 million (37%) to \$2.3 million (51%) for the 40  $\mu$ g/L option, and about \$2.3 million (66%) to \$2.6 million (87%) for the 80  $\mu$ g/L option.

Exhibit 3.1
EPA's total annual cost estimates for uranium MCL options
25-100 and 101-500 population served categories
(aggregate of groundwater and surface water systems)

MCL option	MCL =20 μg/L	MCL = 40 μg/L	MCL = 80 μg/L
Total annual costs (dir	rect proportional occurre	nce): \$/yr²	
NODA	8,400,000	4,500,000	2,800,000
Final rule	7,500,000	2,200,000	240,000
Total annual costs (log	g normal occurrence): \$/y	r <sup>a</sup>	
NODA	8,000,000	4,900,000	3,500,000
Final rule	7,100,000	3,100,000	1,200,000

a. Values rounded to two significant figures.

### **EVOLUTION OF EPA'S APPROACH**

Comparison to the NODA approach. Exhibits 3.2 through 3.5 provide comparisons of EPA's cost estimates (both direct proportional and log normal cases) for the NODA and the final rule for the two smallest system size categories. Exhibits 3.2 and 3.3 are for groundwater systems and surface water systems in the 25 to 100 population served category, and Exhibits 3.4 and 3.5 are for groundwater systems and surface water systems in the 101 to 500 population served category.

These exhibits show that EPA has removed the monitoring costs from the compliance cost analysis and that minor changes have occurred in the annualized capital and annual O&M costs. Changes in the annual costs are discussed separately for each category.

Exhibit 3.2 summarizes these costs for groundwater CWS serving populations of 25 to 100. Note that there is a fairly significant increase in annualized capital and annual O&M costs from the NODA and the final rule, especially for the 20 µg/L MCL option, where annualized capital costs increase by over 80% and annual O&M costs increase by 50 to 60%. However, the monitoring costs control the overall annual cost differences.

Exhibit 3.2 Compliance costs for groundwater CWS: 25-100 persons served category

	Direct pro	portional	Log no	ormal
Cost parameter	NODA	Final rule	NODA	Final rule
20 μg/L MCL				
Annual capital	511,761	914,095	457,562	860,920
Annual O&M	787,528	1,191,909	696,933	1,110,002
Annual monitoring	793,578	0	770,307	0
Total annual costs	2,092,867	2,106,004	1,924,802	1,970,922
40 μg/L MCL				
Annual capital	169,806	254,375	203,541	374,771
Annual O&M	284,584	350,877	312,671	485,856
Annual monitoring	678,582	0	679,981	0
Total annual costs	1,132,972	605,252	1,196,193	860,627
80 μg/L MCL				
Annual capital	21,458	26,658	82,691	149,222
Annual O&M	38,563	39,317	128,132	194,521
Annual monitoring	615,566	0	635,903	0
Total annual costs	675,587	65,975	846,726	343,743

Exhibit 3.3 provides a similar summary for surface water CWS serving populations of 25 to 100. In this case, note that including monitoring costs has a major impact on annual compliance costs. Again, there are increases in the annualized capital and annual O&M costs from the NODA and the final rule, but they are more modest. However, the monitoring costs control the overall annual cost differences.

Exhibit 3.4 summarizes these costs for groundwater CWS serving populations of 101 to 500. Note that there is a fairly significant increase annualized capital and annual O&M costs from the NODA and the final rule, especially for the 20  $\mu$ g/L MCL option, where annualized capital costs increase by 33 to 39% and annual O&M costs increase by 27 to 31%. However, the monitoring costs control the overall annual cost differences.

Exhibit 3.3 Compliance costs for surface water CWS: 25 to 100 persons served category

	Direct prop	oortional	Log normal		
Cost parameter	NODA	Final rule	NODA	Final rule	
20 μg/L MCL					
Annual capital, \$/yr	1,522	2,062	6,839	9,983	
Annual O&M, \$/yr	3,426	3,909	14,676	17,830	
Annual monitoring, \$/yr	587,313	0	621,781	0	
Total annual costs, \$/yr	592,261	5,971	643,296	27,813	
40 μg/L MCL					
Annual capital, \$/yr	0	0	2,638	3,772	
Annual O&M, \$/yr	0	0	5,732	6,838	
Annual monitoring, \$/yr	576,529	0	594,109	0	
Total annual costs	576,529	0	602,479	10,610	
80 μg/L MCL, \$/yr					
Annual capital, \$/yr	0	0	885	1,269	
Annual O&M, \$/yr	0	0	1,994	2,356	
Annual monitoring, \$/yr	576,289	0	582,564	0	
Total annual costs	576,289	0	585,443	3,625	

Exhibit 3.4 Compliance costs for groundwater CWS: 101 to 500 persons served category

	Direct prop	ortional	Log no	rmal
Cost parameter	NODA	Final rule	NODA	Final rule
20 μg/L MCL				
Annual capital, \$/yr	1,588,823	2,120,818	1,441,744	2,003,975
Annual O&M, \$/yr	2,535,141	3,217,222	2,265,563	2,977,934
Annual monitoring, \$/yr	906,457	0	879,877	0
Total annual costs, \$/yr	5,030,421	5,338,041	4,587,184	4,981,909
40 μg/L MCL	•			
Annual capital, \$/yr	472,833	587,789	634,899	871,900
Annual O&M, \$/yr	859,822	993,251	1,009,588	1,309,207
Annual monitoring, \$/yr	775,104	0	776,703	0
Total annual costs	2,107,759	1,581,020	2,421,190	2,181,108
80 μg/L MCL, \$/yr				
Annual capital, \$/yr	53,832	61,462	255,116	346,763
Annual O&M, \$/yr	110,907	117,323	410,792	526,270
Annual monitoring, \$/yr	703,125	0	726,355	0
Total annual costs	867,864	178,785	1,392,263	873,033

Exhibit 3.5 provides a similar summary for surface water CWS serving populations from 101 to 500. In this case, note that the inclusion of monitoring costs has a major impact on annual compliance costs. Here, there are decreases in the annualized capital and annual O&M costs from the NODA and the final rule, but they are modest. Again, the monitoring costs control the overall annual cost differences.

Exhibit 3.5
Compliance costs for surface water CWS: 101 to 500 persons served category

	Direct prop	ortional	Log normal		
Cost parameter	NODA Final rule		NODA	Final rule	
20 μg/L MCL					
Annual capital, \$/yr	9,025	8,158	42,040	40,993	
Annual O&M, \$/yr	18,524	17,884	81,976	82,275	
Annual monitoring, \$/yr	670,853	0	710,224	0	
Total annual costs, \$/yr	698,402	26,042	834,240	123,268	
40 μg/L MCL					
Annual capital, \$/yr	0	0	16,056	15,471	
Annual O&M, \$/yr	0	0	31,741	31,585	
Annual monitoring, \$/yr	658,535	0	678,616	0	
Total annual costs	658,535	0	726,413	47,055	
80 μg/L MCL, \$/yr					
Annual capital, \$/yr	0	. 0	5,517	5,344	
Annual O&M, \$/yr	0	0	11,224	11,076	
Annual monitoring, \$/yr	658,261	0	665,429	0	
Total annual costs	658,261	0	682,270	16,420	

Key comments on the NODA approach. EPA received comments on incomplete treatment cost backup (cost curves missing from T&C document) and lack of costs on residuals management. EPA also received comments on the decision tree, especially on use of high selection (34% of systems) for nontreatment options. In addition, the Agency received comments on the lack of transparency of its cost aggregation modeling (e.g., see Response to Comments Document, Section 20, U.S. EPA, 2000d).

Degree to which the approach in the final rule reflects public comments. EPA indicated that it had revised its treatment costs to reflect public comments; however, it did not adjust its decision tree for nontreatment options.

In general, EPA was basically defensive of its position or nonresponsive to comments. In one case (Comment No. 20.C.2, AWWA's detailed comments on EPA's cost assumptions), the EPA response refers the reader back to another comment (Comment No. 16.4), which concerns the MCL for beta/photon emitters.

### **EVALUATION AND RELIABILITY OF THE EPA RESULTS**

The Agency's efforts on this rule are particularly disappointing when compared with other recent rulemaking efforts. The major transparency issue is that EPA's cost estimates cannot be replicated. Thus, it is not possible to evaluate why the treatment costs changed between the NODA and the final rule, and why these costs increased for the groundwater systems and go up and down for the surface water systems. The exclusion of monitoring costs is discussed in Chapter 4.

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In addition, there are a number of issues regarding the Agency's cost assumptions that differ from other rules. One key issue is the high percentage of systems that EPA believes will implement nontreatment options. EPA believes 17% of affected systems will blend/regionalize and another 17% will drill new wells (alternative source). Blending seems unreasonable for very small systems unless another source is readily available, although it is more reasonable for large systems with many wells. The drilling of new wells in areas of high uranium has been discounted, even though, for naturally occurring arsenic, the Agency has assumed that option would not be productive. EPA bases its assumption on information from the California Department of Health Services that many systems originally drilled new wells when California implemented its uranium standard in 1989. However, EPA appears to be ignoring further comments from the California DHS on the NODA (Comment No. 20.B.7) that an unintended consequence of this action is that after some period of years, higher uranium levels are appearing in many wells and these systems are encountering significant logistical and economic problems and are now considering treatment for compliance. This is typical for naturally occurring contaminants. Thus, EPA appears to be recommending an option that may be doomed to failure. In addition, an analysis of uranium occurrence in California wells performed for this study indicates that most of the systems with uranium above 30 µg/L serve populations above 500 (see Appendix A).

Adherence to best practices and guidance. EPA has handled a number of cost issues differently in this rule than others, although it is not clear why. The biggest issues regard the decision tree and residuals management assumptions. Exhibit 3-6 provides a comparison of EPA's general cost assumptions for uranium with those in the final arsenic rule (U.S. EPA, 2001a).

Exhibit 3-6 Comparison of EPA's cost assumptions for uranium and arsenic CBAs

Cost assumption category	Uranium	Arsenic Supplemented NIRS with other occurrence data	
Occurrence	Relied on NIRS data and questionable distributions		
Compliance responses	Included unusually high selection (34%) of non-treatment responses	Included no non-treatment responses, only treatment responses	
Decision tree	Specific treatment technologies difficult to ascertain; specific waste disposal technologies not identified	Specific treatment and waste disposal technologies identified	
Aggregation model	Aggregation methodology for cost aggregation not identified	Aggregation model identified	

Transparency and replicability. EPA has not really made enough information available to replicate its cost estimates. Some of the missing information include the following:

- The aggregation model is not identified (e.g., was EPA's SafeWater Suite used?).
- Several of the treatment options are grouped into a category of softening/iron removal, which includes some technologies that are not appropriate for uranium removal. In addition, the specific technologies used in the Agency's cost estimates cannot be discerned.
- The residual management options selected for treatment technologies used in the cost estimate are not identified and thus it is impossible to determine what costs were used for residuals management.

The removal of the monitoring costs from the analysis is transparent to anyone that reviews the detailed cost tables.

### **EPA'S INTERPRETATION OF RESULTS**

EPA concludes that it has used the best information available to it and has provided sufficient information for any interested party to replicate its cost analysis. The Agency has justified its removal of monitoring costs from the compliance cost estimates as not really being part of the analysis and, in any case, being a small portion of the costs (see Chapter 4 for additional discussion).

### OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D. Just barely. EPA has done a poor job of developing and describing its cost analysis, especially when compared to other rulemaking efforts.

### **CHAPTER 4**

### **MONITORING COSTS**

### (AND THEIR INCLUSION IN THE URANIUM CBA)

### **ISSUE**

EPA's estimated monitoring costs went down appreciably between the NODA and the final rule. It also appears that EPA has not considered monitoring costs in evaluating the CBA tradeoffs of alternative uranium MCL options. This would be inappropriate, and also reflects a change in approach relative to the NODA. This chapter examines this issue and provides a critique.

### EPA'S APPROACH AND FINDINGS (FINAL RULE)

In the final rule, EPA presented monitoring costs for the uranium MCL of 30  $\mu$ g/L as part of the overall monitoring cost of the rule and did not consider monitoring costs in the cost-benefit analysis. EPA's Economic Analysis (see Exhibit 4-10 of EPA 2000e) indicates that the "average present value of annual monitoring costs over a 23-year period" for uranium would be \$165,000 for the 30  $\mu$ g/L MCL. Although not calculated or presented by EPA, the annual monitoring costs for the 30  $\mu$ g/L uranium MCL, based on the NODA, would be about \$5,100,000. This would add about 10 percent to EPA's cost estimate of \$51,000,000 per year cited in the final rule for compliance with the uranium MCL of 30  $\mu$ g/L (note that the estimate is \$49,700,000 in the Economic Analysis).

### **EVOLUTION OF EPA'S APPROACH**

Between the NODA and the final rule, EPA developed an Information Collection Request (U.S. EPA, 2000h), which EPA cites in the Economic Analysis (U.S. EPA, 2000e). The ICR provides the basis for the revised monitoring costs or the 30  $\mu$ g/L MCL used in the final rule.

Comparison to the NODA approach. Exhibit 4.1 compares EPA's estimates of total annual costs for MCL options of 20 µg/L, 40 µg/L, and 80 µg/L from the Preliminary HRRCA (NODA) and the Economic Analysis (final rule) for the direct proportional and the log normal occurrence distributions. This exhibit shows that EPA did not include the monitoring costs in the final rule costs attributed to complying with any MCL option. The effect of removing the monitoring cost from the analysis becomes more important for the direct proportional occurrence cases and more important as the MCL increases. For example, for the 80 µg/L MCL option, the annual costs in the NODA are about \$5 million and \$30 million for the direct proportion and log normal occurrence cases, respectively, while the corresponding annual costs for the final rule are about \$240,000 and \$25.5 million. The differences of about \$4.5 million correspond roughly to the monitoring costs included in the NODA analysis. As discussed in Chapter 3, there are some overall increases in annualized capital and annual O&M costs from the NODA to the final rule.

Exhibit 4.1 Comparison of monitoring cost included in the CBA from the NODA and the final rule

Cost parameter	Direct proportional		Log normal	
	NODA	Final rule	NODA	Final rule
20 μg/L MCL				
Annual capital, \$/yr	11,056,377	11,062,035	58,753,136	63,802,746
Annual O&M, \$/yr	15,327,095	14,393,211	92,795,827	91,583,169
Annual monitoring, \$/yr	5,219,269	0	5,478,941	0
Total annual costs, \$/yr	31,602,741	25,455,246	157,027,904	155,385,915
40 μg/L MCL				•
Annual capital, \$/yr	642,639	842,164	24,489,472	25,923,572
Annual O&M, \$/yr	1,144,406	1,344,128	38,460,142	37,873,457
Annual monitoring, \$/yr	4,891,622	0	5,051,315	0
Total annual costs, \$/yr	6,678,667	2,186,292	68,000,929	63,797,029
80 μg/L MCL			, ,	, , , , , , , , , , , , , , , , , , , ,
Annual capital, \$/yr	75,290	88,120	9,720,428	10,530,897
Annual O&M, \$/yr	149,470	156,640	15,348,851	15,009,606
Annual monitoring, \$/yr	4,754,812	0	4,855,802	0
Total annual costs, \$/yr	4,979,572	244,760	29,925,081	25,540,503

Key comments on the NODA approach. Comments on the NODA note that EPA should include labor costs for monitoring as well as analyses costs as was done for the Ground Water Rule proposal (Comment No. 17.1). These costs should be included in the CBA along with other administrative costs, as has been done in recent rule making.

In addition, other comments (e.g., from the California Department of Health Services; Comment No. 16.3) recommended that EPA use gross alpha screening to reduce the monitoring burden on water utilities with low uranium levels.

Degree to which the approach in the final rule reflects public comments. While EPA did not include the monitoring costs in the CBA, revised monitoring costs were included in the overall cost of the rule. In addition, the Agency indicates that it significantly reduced the monitoring burden for uranium monitoring by adopting changes in the gross alpha screening procedures and reduced the frequency for alpha monitoring for systems below the uranium MCL. The basis for the revised monitoring costs for the 30  $\mu$ g/L MCL is included in the Information Collection Request (U.S. EPA, 2000h).

### **EVALUATION AND RELIABILITY OF THE EPA RESULTS**

Adherence to best practices and guidance. EPA has treated monitoring costs differently in this final rule than it has in other recently proposed or final rules on drinking water regulations in that they are not included in the CBA. We note, for example, that the Final Arsenic Rule (U.S. EPA, 2001a) includes monitoring and administrative costs in the compliance costs for the CBA.

EPA has included monitoring costs for uranium with the cost for monitoring other radionuclides. These costs represent the "average present value of annual monitoring costs over a 23-year period." The ICR includes the methodology for calculating costs in this manner and the actual analysis for the 30 μg/L. EPA provides an estimate of \$165,000/year for the 30 μg/L MCL, which it indicates would not substantially affect the CBA. While EPA's economic *Guidelines* allow use of the average present value method to estimate costs and benefits, the guidance indicate this should be done only when all costs and benefits are computed on the same basis. For this rule, only the monitoring and administrative costs are computed using this

approach. The corresponding undiscounted monitoring costs, on a 20 year basis, would be about \$194,000 per year.

Transparency and replicability. An examination of EPA's analysis of uranium monitoring costs for the 30  $\mu$ g/L MCL in the ICR indicates that it is transparent and replicable. EPA's effort in this respect is very good, especially when compared with the treatment cost estimates.

### EPA'S INTERPRETATION OF RESULTS

Appendix B provides an analysis of the uranium monitor costs presented in the ICR. That analysis suggests that the EPA costs reflect the minimum monitoring costs associated with use of grandfathering some of the initial monitoring data (collected between years 2000 and 2003, but attributed to the old rule), maximum substitution of gross alpha data (when gross alpha  $\leq$  15 pCi/L) for uranium analyses, and compositing of samples after the initial monitoring period. Although the final rule includes these provisions, states strictly following EPA's "Implementation Guidance for Radionuclides" (U.S. EPA, 2000i) would likely require additional uranium monitoring (see Appendix B). Annual monitoring costs for the 30  $\mu$ g/L MCL under that scenario could be as high as \$1,800,000 per year (less than 4% of other annual compliance costs).

EPA has focused its uranium monitoring analysis on the 30  $\mu$ g/L MCL and thus has excluded it from the CBA. For completeness, monitoring costs should be included in the CBA analysis, as has been done for other recent rules. EPA indicated that the monitoring costs were not significant compared with the treatment costs for the 30  $\mu$ g/L MCL and it would not have a major impact on the CBA. This might not be true for the 40  $\mu$ g/L and 80  $\mu$ g/L potential MCLs, particularly when the direct proportional occurrence model is used. For example, the \$194,000 per year monitoring cost at 30  $\mu$ g/L is almost comparable to EPA's direct proportional annual treatment of \$245,000 per year for the 80  $\mu$ g/L MCL option.

### OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: C+. EPA appears to have reduced the monitoring burden for uranium from the NODA to the final rule, as recommended by some commentators. EPA is commended for this effort. However, comparison of the ICR analysis and EPA's Implementation Guidance for Radionuclides suggests that, based on state interpretation, monitoring costs may be higher.

In addition, EPA has excluded monitoring costs from the CBA. In addition, EPA has discounted these costs in concert with annualizing them. Discounting of monitoring and administrative costs in the ICR does not appear to be warranted for this rule, as this approach puts monitoring costs on a different basis than annualized treatment costs and benefits.

### **CHAPTER 5**

### AFFORDABILITY: CUMULATIVE IMPACTS AND THE WATER BILL BASELINE

### ISSUE

An important issue is how EPA assesses the affordability of its drinking water regulations. A key concern is whether the Agency considers the cumulative impact of its rules, or examines the uranium standard as if it were the only new cost-imposing action on water utility customers. This chapter examines and evaluates how EPA handles this matter in the uranium rulemaking.

### EPA'S APPROACH AND FINDINGS (FINAL RULE)

Approach. EPA agrees that it would be best to look at cumulative affordability, since it is a realistic indicator of affordability (U.S. EPA, 2000c). In practice, EPA includes a "water bill baseline" in its affordability assessments, which includes cumulative impacts from existing final regulations.

The affordability assessment supporting the uranium small systems compliance technology list is based on the current baseline, which is described in "Variance Technology Findings for Contaminants Regulated Before 1996" (U.S. EPA, 1998). Supposedly, as future rules that affect small water systems are promulgated (including this one), this baseline will be revised. When a rule is promulgated, the water bill baseline will be increased and the estimate of affordability decreases, the details of which depend on the percentages of systems impacted and the estimates of the annual per household costs associated with the regulation.

Baselines for the affordable technology analysis were determined using annual household consumption, current annual water bills, and median household income. Separate baselines for these parameters were established for each of the three system size categories. Annual household consumption was used to convert treatment cost increases into household impacts. Current annual water bills were subtracted from the affordability threshold to determine the available expenditure margin. The median household income was used to translate the threshold percentage into an actual dollar figure.

Results. The national-level affordability criteria are based on an affordability threshold of 2.5% of the median household income. Baselines values for current water bills range from 0.65% of median household income for large systems (serving 3,301 to 10,000 customers) to 0.69% for small systems (serving 25 to 500 customers) (U.S. EPA, 1998).

Applying these criteria, EPA uses a threshold of \$500 in increased costs per household per year. In other words, technologies that increase costs by less than this amount are considered affordable. EPA's estimates of per household costs for the uranium rule are below a maximum of about \$210 for the smallest systems, and thus compliance with the uranium requirements was determined to be affordable and variances would not be required (U.S. EPA, 2000e).

### **EVOLUTION OF EPA'S APPROACH**

Comparison to the NODA approach. The same approach was applied in the NODA.

Key comments on the NODA approach. Baselines do not include the impacts of proposed rules. Many potentially expensive rules are proposed that will affect small groundwater-based community water systems in the near future (e.g., radon, arsenic, and groundwater disinfection). The cumulative impacts could be significant in any small community water system that is affected by more than just the uranium rule.

Within the radionuclides rulemaking, however, EPA did address the uranium rule in addition to "closure of the radium loophole." The Agency states that radium and uranium tend not to co-occur at elevated levels in the same system, and add that uranium can be removed by many of the technologies already included on EPA's list of compliance technologies.

Degree to which the approach in the final rule reflects public comments. EPA's response to comments on affordability indicates that it will update the baseline to reflect cumulative impacts, but only after a rule is promulgated. With several potentially costly rulemakings in progress at the same time, however, waiting until promulgation may not provide an adequate picture of the affordability problem, especially as faced by customers of small systems. In addition, the Agency should conduct sensitivity analyses over a range of affordability thresholds (e.g., the traditional 2% of income in addition to the recent move to 2.5% measure).

### **EVALUATION AND RELIABILITY OF EPA RESULTS**

Adherence to best practices and guidance. With a modest effort, EPA could easily address cumulative impacts of a range of proposed rules that are simultaneously in progress. This could be a simple sensitivity analysis. Allowing more flexibility for baseline estimates would offer more accurate predictions of future household costs.

In addition, EPA's current analyses focus only on households of median income. This narrow perspective fails to reflect hardships that a rule may impose on households in poverty.

Third, the affordability threshold of 2.5% is an arbitrary measure of "affordability." There is no scientific or economic basis for its use other than as a consistent, subjective, and convenient benchmark. At a minimum, EPA should use thresholds over a range, and not solely the arbitrary 2.5% of median income.

Fourth, the affordability analysis must rely on EPA's estimates of the costs of compliance. If these estimates are unreliable or omit several important costs borne by households because of the rule (e.g., monitoring costs), then the affordability analyses will be misleading.

Transparency and replicability. The analyses are fairly transparent, if one accepts the basic cost estimates and other data used at face value.

### **EPA'S INTERPRETATION OF RESULTS**

EPA's concludes the uranium rule is affordable to households with median incomes. This interpretation is dependent on whether EPA's costs estimates prove to be reasonably accurate and complete.

### OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D+. The rule may not be affordable for households below the poverty level. One study on the arsenic rule revealed affordability concerns for households that would see water costs increase by more than 0.5% of their income for households with incomes below the poverty level (Rubin, 2000). The use of a narrowly defined baseline water bill is also a problem that could easily be addressed with a small increase in effort. In addition, if costs are underestimated

and other proposed rules take effect that raise baseline costs, the rule may not be affordable to median incomes.

#### CHAPTER 6

## **HUMAN HEALTH BENEFITS:**

## USE OF LATENCY AND DISCOUNTING IN VALUING PREMATURE CANCER FATALITIES AVOIDED

## **ISSUE**

In the uranium rulemaking, EPA has valued future cancer cases avoided as if there were no latency period. This means that near-term compliance costs are inappropriately compared to health risk reduction benefits that actually will accrue many years (e.g., decades) into the future. This skews the cost-benefit comparison relative to alternative public health actions that would generate more near-term health benefits.

AWWA and other parties have provided extensive comment on this issue, and it also has been addressed by a recent Science Advisory Board (SAB) report, An SAB Report on EPA's White Paper Valuing the Benefits of Fatal Risk Reductions (U.S. EPA, 2000b). The well-established "best practice" (as recommended by SAB) is to account for latency periods in relevant cancer risk settings, and discount these future benefits back to present value using the same rates that are applied to costs and other benefits. In this chapter we review the manner in which the final rule addresses this issue, and the justification EPA provides for its approach.

#### EPA'S APPROACH AND FINDINGS (FINAL RULE)

Consistent with the NODA and other prior rulemakings (e.g., for the proposed rules for radon and arsenic), EPA has not applied latency periods for the delayed onset of cancers associated with uranium. By implicitly assigning a zero latency period to the cancer risks, there is no discounting of the cancer benefits. This makes the cancer benefits appear to be greater than they really are, since risks borne 10, 20, or more years in the future have a lower (discounted) present value than risks reduced immediately.

It should be noted that in the "final" rule for arsenic, as published in the *Federal Register* on January 22, 2001 (66 FR 6978), EPA did take a step in the proper direction by providing some latency- and discount-adjusted fatality risk values as part of a sensitivity analysis.

#### **EVOLUTION OF EPA'S APPROACH**

Comparison to the NODA approach. The approach used in the final rule is identical to the approach applied in the NODA. As in other recent, prior rulemakings, the Agency solicited comment on the issue of latency and discounting as part of the NODA.

Key comments on the NODA approach. As noted above, the approach used (of not applying latency and discounting) is contrary to established best practices for economic analysis, and leads to an overstatement of benefits in cases where the risk reductions are cancers that typically occur after a long latency period.

Degree to which the approach in the final rule reflects public comments. The approach in the final rule does not respond to public comments on this subject (e.g., as explicitly raised by AWWA). The EPA Comment-Response Document simply states that since the principal benefits are unquantified kidney toxicity risk reductions, the issue of adjusting the cancer risk values is irrelevant.

This EPA response is naive, however. First, EPA should strive to do the analyses properly, regardless of how the numbers may or may not influence the outcomes. The Agency should follow its own guidelines and the recommendations of the SAB (U.S. EPA, 2000a, 2000b). Second, the results do influence how the "break-even" analyses can be used to interpret the cost of reducing risks of renal toxicity (see Chapter 8).

## **EVALUATION AND RELIABILITY OF EPA RESULTS**

EPA's results are not accurate because the Agency's approach does not adhere to sound practices. Fatal cancer cases avoided are valued at \$5.9 million (1998 dollars), whereas a more suitable latency-adjusted and discounted Value of Statistical Life (VSL) value would be in the range of \$1.5 to \$2.5 million (depending on latency period, discount rate, and other factors).

Adherence to best practices and guidance. By not applying latency scenarios and not appropriately discounting delayed onset cancers, EPA has failed to adhere to its own Guidelines (U.S. EPA, 2000a) and to the recommendations of the SAB's Environmental Economics Advisory Committee (EEAC, U.S. EPA, 2000b). The EPA approach in the final rule is also at

odds with well-established and generally accepted standard practices and empirical evidence from peer-reviewed published research.

Transparency and replicability. EPA's valuation results for reduced risks of premature fatalities are replicable and transparent (but are not correct, as per above discussion).

## **EPA'S INTERPRETATION OF RESULTS**

Because the cancer benefits are so small relative to costs, net benefits are negative (costs exceed benefits) by a large margin (even with EPA's use of unadjusted VSLs).

## OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: F. For the final uranium MCL, EPA's performance is poor on this issue. The Agency has shown modest improvement in its use of latency-adjusted and discounted VSLs in a subsequent rulemaking (e.g., the arsenic rule as published in the FR, January 22, 2001). EPA must adhere to standard best practices in all its CBAs.

#### **CHAPTER 7**

## **BENEFIT-COST COMPARISON:**

## PRESENTATION AND USE OF INCREMENTAL COST-BENEFIT ANALYSIS

**ISSUE** 

In the NODA and other recent rulemakings, EPA has not provided or used a meaningful comparison of incremental benefits to incremental costs. The incremental approach is the suitable conceptual way to use CBA, and is mandated under the 1996 Amendments to the Safe Drinking Water Act. This chapter examines the extent to which the final rule provides and interprets an incremental CBA perspective.

## EPA'S APPROACH AND FINDINGS (FINAL RULE)

In the final rule, EPA presents a comparison of incremental benefits to incremental costs, with the benefits limited to cancer risk reductions (note that kidney toxicity benefits are not readily quantifiable; see Chapter 8). The analysis, as shown in the *Federal Register* as Exhibit I-2 (65 FR 76708, at page 76714), reveals that regardless of the MCL option, the incremental net benefits (incremental benefits minus incremental costs) are negative.

Interestingly, EPA does not report net benefit findings — it only shows incremental benefit and costs, but not the difference between the two. Nonetheless, it is readily apparent that incremental costs outweigh incremental monetized benefits by a large margin (by a factor of well over 10) regardless of the regulatory increment.

Noteworthy is the fact that EPA's incremental analysis does not include consideration of the 40  $\mu$ g/L option that was developed as part of the NODA. Instead, the EPA incremental analysis is split into two perspectives. One perspective shows the increments as (1) baseline to an MCL option of 80  $\mu$ g/L, (2) 80  $\mu$ g/L to 30  $\mu$ g/L, and (3) 30  $\mu$ g/L to 20  $\mu$ g/L. The second perspective goes directly from baseline to 30  $\mu$ g/L, and then from 30 to 20  $\mu$ g/L. The omission of the 40  $\mu$ g/L option from this analysis, especially under the second perspective, defeats the true purpose of an incremental analysis by omitting key steps (MCL options) of 80  $\mu$ g/L to 40  $\mu$ g/L, and 40  $\mu$ g/L to 30  $\mu$ g/L.

Another key omission from the incremental analysis is that no attempt was made to evaluate the nonquantified kidney toxicity benefits within the context of an incremental analysis. Even though these potential risk reductions could not be monetized, informative ways of considering the MCL-related exposure reductions can be derived from an incremental CBA (as discussed in Chapter 8, and demonstrated in Appendix C).

#### **EVOLUTION OF EPA'S APPROACH**

Comparison to the NODA approach. The NODA presented no incremental analyses. The NODA approach also did not include an assessment of the 30  $\mu$ g/L option, which was developed in the final rule as an artificial construct based on an interpolation of data from the 20  $\mu$ g/L and 40  $\mu$ g/L options. The 40  $\mu$ g/L option was not included in the incremental analysis accompanying the final rule.

Key comments on the NODA approach. Comments submitted on the NODA note that an incremental analysis was missing from the NODA, and that such an analysis would be valuable and was required by the statute. The significant majority of comments also recommended EPA use its CBA-based discretionary authority to set an MCL of 40  $\mu$ g/L (or 80  $\mu$ g/L) rather than the technically feasible option of 20  $\mu$ g/L, based on the CBA results and other information presented in the NODA.

Degree to which the approach in the final rule reflects public comments. EPA added an incremental analysis in the final rule, as described above. The addition of an incremental CBA exhibit in the final rule is a welcomed step forward. However, problems with the final rule's approach to the incremental CBA severely limit the value of incremental analysis provided. One key problem is the omission of the 40 µg/L option from the incremental analysis, and another deficiency is the lack of effort to assess nonquantifiable renal toxicity benefits within an incremental CBA framework (both issues are discussed in greater detail below).

#### **EVALUATION AND RELIABILITY OF THE EPA RESULTS**

Adherence to best practices and guidance. It is noteworthy that increments considering the 40 µg/L option (which was developed in the NODA) are not shown or considered in the final

rule. This is unfortunate because the intent and value of an incremental analysis is to evaluate the worth of each potential regulatory step rather than to lump the steps together into an indistinguishable, larger regulatory action. Further, EPA has developed estimates of the occurrence, costs, and benefits of the 40  $\mu$ g/L option, since this was one of the three options developed under the NODA-related analyses It would be very useful to see how the 80  $\mu$ g/L to 40  $\mu$ g/L MCL increment compared to the 40 to 30  $\mu$ g/L and 30 to 20  $\mu$ g/L increments (as demonstrated in Appendix C).

Further, the final MCL of 30  $\mu$ g/L was not considered in the NODA. All the cost and benefit information for the 30  $\mu$ g/L option was deduced by EPA using a questionable interpolation of the occurrence results the Agency generated for the 40  $\mu$ g/L and 20  $\mu$ g/L options (see Chapter 2 for additional details). The fact that the results for 30  $\mu$ g/L are an artificial construct of the Agency's data on the 40 and 20  $\mu$ g/L options makes the omission of the 40  $\mu$ g/L option from the incremental analyses even more problematic.

Finally, the Agency made no effort to view its nonquantifiable renal toxicity benefits within the incremental CBA framework. As described in greater detail in Chapter 8, there are established ways in which analysts can explore nonquantified benefits (and costs) to provide valuable information to decision-makers and stakeholders. One such approach (a "break-even" assessment) was demonstrated in AWWA's submitted comments. EPA dismissed this suggestion as "irrelevant" (U.S. EPA, 2000d).

Transparency and replicability. The incremental CBA is transparent and replicable, once one has the total cost and benefit estimates EPA developed. Some of the underlying cost and benefit estimates are not very transparent and replicable, however, as discussed elsewhere in this report.

#### **EPA'S INTERPRETATION OF RESULTS**

EPA "believes that 30  $\mu$ g/L maximizes the net benefits and is protective of kidney toxicity with an adequate margin of safety" (U.S. EPA, 2000d, p. 9-13). Since the Agency's incremental CBA omits the 40  $\mu$ g/L option, and does not attempt to evaluate renal toxicity in any fashion, EPA's interpretation is difficult to evaluate (and Chapter 8 provides further discussion of this issue).

The Agency also uses its limited version of an incremental CBA (from Exhibit I-2 in the Federal Register) to help bolster its position that an MCL of 20  $\mu$ g/L is not warranted. In this regard, the Agency is correct, because its exhibit shows that moving from baseline to 30  $\mu$ g/L is better from a net benefits perspective than proceeding onward from 30  $\mu$ g/L to the technically feasible option of 20  $\mu$ g/L.

## OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D. EPA avoids a failing grade by at least presenting and discussing an incremental CBA in the final rule. However, the analysis is flawed and needs to be improved in several important ways. In particular, more MCL options (incremental steps) need to be included (especially because EPA already has benefit-cost results available for interim MCL options), and some semi-quantitative evaluation of potentially important but nonmonetized benefits should be assessed as well.

#### **CHAPTER 8**

## CONSIDERATION OF NONQUANTIFIED BENEFITS: INCLUSION AND INTERPRETATION OF URANIUM KIDNEY TOXICITY

#### **ISSUE**

The health benefit that serves as the principal basis for the uranium rule is a reduced risk of potential kidney toxicity. This potential health benefit cannot be quantified as estimated numbers of cases avoided. This is because (1) there is considerable uncertainty about what levels of exposure are "safe" (pose no risk of cellular changes within kidneys of highly exposed and highly sensitive individuals), and (2) it is unknown whether the potential for cellular level changes within the kidney are associated with an increased risk of a manifested adverse health effects (i.e., the potential change in kidney cells has not been associated with any increased risk of kidney disease).

Since the level of risk (if any) is not quantifiable as a number of adverse health effect cases (kidney illnesses) avoided, it is not possible to directly assign monetary values to these risk reduction benefits. EPA uses this fact as a rationale for not performing any useful analysis of the benefits and costs of the rule. EPA dismisses an AWWA illustration of how this might be done as being "not relevant." Yet at the same time, EPA claims to use the CBA as the basis for setting the MCL at 30  $\mu$ g/L rather than at the level technically feasible (which EPA claims is 20  $\mu$ g/L). There is a fundamental flaw in EPA's logic here, since on the one hand EPA claims CBA cannot be done, and on the other hand, the Agency claims it relied on CBA to set the MCL and "believes 30  $\mu$ g/L maximizes the net benefits" (U.S. EPA, 2000d).

## **EPA'S APPROACH AND FINDINGS (FINAL RULE)**

In the NODA and final rule, EPA compared costs to benefits that were monetized only for cancer-related fatalities. Possible risks associated with kidney toxicity were described qualitatively. Given how small the cancer-related benefits were relative to costs, EPA justified its proposed MCL on the nonquantified and nonmonetized risk reductions for kidney toxicity.

EPA has established that a drinking water equivalent level (DWEL) concentration of 20 μg/L would be safe (i.e., pose zero risk of any cellular level changes within the kidney) to even highly sensitive and highly exposed individuals, with an adequate margin of safety. This "zero risk" level was derived by EPA based on its standard but highly conservative risk assessment techniques, including use of an uncertainty factor of 100 applied to the dose-response data and an exposure assumption of 2 L/day of water consumption (which approximately reflects a 90th percentile of per capita tap water consumption) over a 70 year lifetime. Using these precautionary principle assumptions is suitable for establishing a "zero risk" level for any plausible human exposure/sensitivity scenario, but overstates the anticipated benefits for the population (e.g., see GAO, 2000).

EPA recognizes that the compounded effect of the conservative assumptions underlying the DWEL implies that zero risk (or, at worst, de minimus risk) can be achieved with drinking water concentrations above 20  $\mu$ g/L. The Agency explicitly uses this fact to establish an MCL above 20  $\mu$ g/L. EPA states that there is "not a predictable difference in health effects due to exposures between the DWEL of 20  $\mu$ g/L and a level of 30  $\mu$ g/L" (U.S. EPA, 2000c, p. 76713). EPA goes on to add, "Given that the uncertainty factor of 100 provides a relatively wide margin of safety, the likelihood of any significant effect in the population at 30  $\mu$ g/L is very small. EPA thus believes that the difference in kidney toxicity risk for exposures at 20  $\mu$ g/L versus 30  $\mu$ g/L is insignificant" (U.S. EPA, 2000c, p. 76714). This begs the question, If 30  $\mu$ g/L is indistinguishable from 20  $\mu$ g/L in terms of posing any risks to health, then is there any basis for believing that 40  $\mu$ g/L poses any real risks of renal toxicity compared to the DWEL of 20  $\mu$ g/L?

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#### **EVOLUTION OF EPA'S APPROACH**

Comparison to the NODA approach. EPA's approach in the final rule is the same as provided in the NODA. In essence, the Agency relies on the fact that the kidney toxicity benefits cannot be directly monetized as a rationale for its not exploring very simple and informative CBA-related techniques, such as the "break-even" approach demonstrated in AWWA's submitted comments.

Key comments on the NODA approach. AWWA's comments on the NODA demonstrated how the nonmonetized kidney benefits could still be evaluated within the CBA

context, and revealed that the then-proposed MCL of 20 µg/L could not be justified on the basis these benefits. The approach demonstrated by AWWA (and updated here, in Appendix C) show the cost per person of getting all individuals exposed above the "zero risk" level at baseline down to below 20 µg/L. This cost per person exposed above the safe "oral reference dose" is approximately \$200,000 for MCLs of 80 µg/L or 40 µg/L (which, as a point of reference, is approximately twice the cost to treat a cancer patient or to provide a kidney transplant with a year of follow-up medical care). This cost increases to approximately \$2 million per person at MCL options of 30 µg/L or less.

The NODA comments thus indicated that EPA could easily use its data to estimate the cost of reducing a uranium exposure from above the "zero risk" level to below that level. These are costs to reduce exposures that may pose a risk of cellular level kidney changes in a small fraction of the exposed group, which in turn may or may not manifest in a kidney disease for some fraction of those people who have cellular changes. It is difficult to imagine that society is better off reducing exposure for one person who faces a very low (perhaps negligible) risk of suffering a kidney disease than it would be investing the same funds in treating two or more known patients with manifested cancers.

Degree to which the approach in the final rule reflects public comments. EPA's final rule does not appear to have taken the AWWA and related comments and supporting analyses into account. EPA's response claims that the "break-even" analysis used by AWWA to interpret the CBA data is "not relevant" (U.S. EPA, 2000d, p. 9-35), and the Agency makes no attempt to interpret the kidney toxicity information in a systematic or informative manner.

#### **EVALUATION AND RELIABILITY OF THE EPA RESULTS**

EPA's approach is to overlook the possibility of providing informative analysis. Simple and well-established techniques can be used (as demonstrated in AWWA's submitted comments to the NODA, and updated in Appendix C) to provide insights or whether an unquantifiable risk reduction may be attained at a reasonable cost. EPA has opted to ignore this possibility, and instead leaves the analysis vague and incomplete. Whether intentional or not, the EPA approach provides greater latitude for EPA decision-makers, but also appears to lead to an MCL that is most probably a relatively poor investment in public health. The Agency's approach also may

leave EPA open to legal challenge in terms of its inconsistent (and potentially arbitrary) approach related to using the CBA to set the MCL.

Adherence to best practices and guidance. Best practice suggests that some semiquantitative effort be made to evaluate the data for nonmonetized benefits, because often some informative inferences can be made even when some key outcomes cannot be quantified. EPA has failed to consider this option, and considers it "irrelevant."

Transparency and replicability. Since EPA makes no effort to analyze its renal toxicity data in a CBA context, issues of transparency and replicability do not apply.

#### EPA'S INTERPRETATION OF RESULTS

EPA's statement that "the difference in kidney toxicity risks for exposures at 20  $\mu$ g/L versus 30  $\mu$ g/L is insignificant" is useful, valuable, and almost certainly correct. However, this opens the door to asking relevant and legitimate questions such as, At what level do the risks become distinguishably different from zero (or *de minimus*) levels? and To what degree are the risks and benefits at an MCL of 40  $\mu$ g/L different or distinguishable from the benefits derived at an MCL of 30  $\mu$ g/L?

#### OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: F. The Agency makes no effort to examine the issue in an objective, informative, semi-quantitative manner (even though some standard techniques are available and were illustrated in public comments the Agency received). EPA hides behind the fact that key benefits are not readily quantified or monetized to justify the MCL it desires. Unquantifiable benefits should never be ignored; however, they likewise should never be used as a "carte blanche" to avoid any meaningful analysis and set a potentially arbitrary MCL.

#### CHAPTER 9

# CONSISTENCY OF EPA'S ANALYSES WITH THE AGENCY'S NEW ECONOMIC GUIDELINES, OTHER DIRECTIVES, AND BEST PRACTICES ISSUE

EPA recently published *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2000a), that are intended to guide how EPA conducts CBAs and interprets them. EPA also receives guidance and directives on CBA-related issues from OMB, SAB, and other parties (e.g., through Executive Orders). This chapter evaluates EPA's approach to the CBA issues addressed in previous chapters to determine if and how it is consistent with best practices and directives, including the Agency's own internal guidance for CBA.

#### **OCCURRENCE**

We are not aware of any EPA, OMB, or other official government guidelines or directives on how to perform occurrence analyses. However, there are accepted professional practices for how to perform any statistical analysis, and EPA's occurrence analyses fall short of the mark in several regards. For example:

- Significant explanatory variables (e.g., geologic province) are omitted, and the only explanatory variable EPA uses is system size (which may not be relevant).
- EPA relies on 2 approaches (direct proportional and lognormal), neither of which appear to fit the data. Nonetheless, EPA states that the two bound the truth (which does not appear supportable) and then interpolates what the Agency calls a "best estimate" by averaging them.

EPA's occurrence work can and should be much more robust and open-minded in the future (see, for example, Raucher et al., 1995).

#### TREATMENT COSTS

We are not aware of any EPA, OMB, or other official government guidelines or directives that focus specifically on how to estimate the costs of compliance. However, standard best practice procedures would be to make the analyses much more transparent and readily replicable. In addition, there is an Awwa Research Foundation *User's Guide* (Raucher et al., 1995) that EPA has followed to some extent in other rulemakings, and the same principles and practices should apply for uranium.

Finally, EPA's Guidelines (U.S. EPA, 2000a) and OMB's Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements (OMB, 2000) provide general input on how cost estimates should be prepared. EPA's annualized costs for uranium MCL compliance deviates from those guidelines because different cost elements are annualized in an inconsistent manner [i.e., the monitoring costs are annualized on a present value basis whereas debt service on capital outlays and annual operation and maintenance (O&M) costs are not]. Further, monitoring costs have been deleted from the annual compliance costs (but were suitable included in the economic analyses accompanying the NODA).

#### **MONITORING COSTS**

We are not aware of any specific guidance from EPA, OMB, or elsewhere that supports deleting monitoring costs from the total costs of compliance. EPA does not include monitoring costs in its cost-benefit comparisons, which is contrary to best practices and inconsistent with how EPA has considered such costs in the NODA and in other rulemakings.

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## **AFFORDABILITY**

EPA's affordability analysis relies solely on (1) baseline household water costs considering promulgated rules only, (2) median household income only, and (3) a 2.5% affordability criterion only. Best practices, as reiterated in the EPA *Guidelines*, would be to conduct sensitivity analyses around these individual and combined assumptions, to determine how much impact the assumptions have on the final outcome.

For example, the 2.5% figure that EPA is now using was first announced in 1998, in its Variance Technology Findings for Contaminants Regulated Before 1996, (EPA 815-R-98-003, 1998). The background work for this, which supported a range of 1.5% to 3.0% of median household income, was completed earlier in 1998, in National-Level Affordability Criteria under the 1996 Amendments to the Safe Drinking Water Act — Final Draft Report (International Consultants Inc., with Jan Beecher, Aug. 19, 1998). Yet in the uranium analysis, EPA does not show results for any benchmark other than 2.5% of median income, even though EPA's prior work supports a range of 1.5% to 3.0%.

#### **HUMAN HEALTH BENEFITS**

EPA's approach to valuing cancer-related premature fatalities avoided is at odds with EPA and OMB *Guidelines*, and SAB recommendations (U.S. EPA, 2000b). Nonfatal cancers also need to be discounted back from age of onset to reflect the range of likely latency periods.

## **BENEFIT-COST COMPARISON**

EPA's comparison of benefits to costs is suitable (and in conformance to statutory mandate) to the extent that it includes some comparison of incremental costs to incremental benefits. The CBA also conforms to some aspects of EPA and OMB *Guidelines* by providing ranges in addition to point estimates, and offering some indication of costs and benefits across systems of different size categories.

However, EPA should have included the full range of MCL options when conducting and portraying the incremental findings, and also offered a broader and more insightful handling of uncertainty (e.g., with broader sensitivity analyses). EPA also falls short of guidance and best practices in terms of its refusal to consider kidney toxicity effects within the CBA context. Even though the renal toxicity risks are not readily quantified, simple methods for taking them into consideration are available, and were in fact offered as illustrations to EPA in public comments.

## CONSIDERATION OF NONQUANTIFIED BENEFITS

The Agency is not in conformance with the OMB *Guidelines* (OMB, 2000) or the spirit of EPA *Guidelines* (U.S. EPA, 2000b) in its handling of unquantified kidney toxicity risks. As OMB states, "if quantification is difficult, you should present any relevant quantitative information along with a description of the unquantifiable effects." (OMB, 2000, p 6). EPA does provide a reasonable discussion of the qualitative aspects, but deemed a simple semi-quantitative approach (as shown in Appendix C of this report) as "irrelevant."

## OVERALL ASSESSMENT OF EPA ANALYSIS

Grade: D. In several regards the Agency adheres to internal and external guidelines and directives. However, important deficiencies remain, such as failing to discount future benefits, using inconsistent approaches for annualizing different cost components, deleting monitoring costs, and omitting available approaches for placing important unquantified benefits within the cost-benefit framework.

## **CHAPTER 10**

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# APPENDIX A OCCURRENCE ISSUES

#### INTRODUCTION

This appendix addresses issues regarding EPA's uranium occurrence estimates in the Final Radionuclides Rule. The key issues evaluated are:

- Do the NIRS uranium data, stratified by system size, provide a good prediction of uranium occurrence?
- Do available state uranium data support EPA's occurrence assumptions?
- Can EPA's interpolation of affected systems vs. MCL option be confirmed?

#### **NIRS URANIUM DATA**

EPA relies entirely on uranium data from its National Inorganics and Radionuclides Survey (NIRS) to predict uranium occurrence in community water systems (CWS) in its Final Radionuclides Rule. The NIRS data are strictly for groundwater systems, so EPA assumed that uranium occurrence in surface water was one-third of the level reported in groundwater, based on a ratio from research conducted by Oak Ridge National Laboratory on uranium in U.S. groundwater and surface water (ORNL, 1981). EPA assumed that the uranium data were stratified by system size and not influenced by other parameters such regional or geological differences. EPA did use this later approach to estimate occurrence in non-transient, non-community water systems (NTNCWS) on a state-by-state basis, as described in Chapter 5 of the Economic Analysis (U.S. EPA, 2000e).

## Comparison of NIRS Uranium and Arsenic Data

Arsenic, a predominantly naturally occurring contaminant like uranium, provides a useful example of how NIRS data compare with other occurrence studies. In its Final Arsenic Rule (U.S. EPA, 2001a), EPA compared the NIRS arsenic occurrence predictions with other

occurrence studies for arsenic. Exhibit A.1 summarizes this comparison. Note that EPA used log normal distributions for arsenic. This exhibit also suggests that NIRS under-predicts arsenic occurrence in groundwater system by a factor of 1.6 to 1.8. In addition, the exhibit suggests that the ratio of groundwater to surface water arsenic occurrence is near 3:1 for lower arsenic concentrations, but moves toward 7:1 as the concentrations (MCL option) increases. Uranium might follow a similar trend.

Exhibit A.1 Comparison of arsenic occurrence estimates

	% of systems with mean exceeding As concentration (μg/L)				
Occurrence study	2	3	5	10	20
Groundwater systems — % > MCL o	ptiona				
EPA — proposed rule (all CWS)	27.2	19.9	12.1	5.4	2.1
EPA — final rule (all CWS)	27.3	19.9	12.1	5.3	2.0
NIRS (all CWS)	17.4	11.9	6.9	2.9	1.1
USGS (all PWS)	25.0	NR	13.6	7.6	3.1
NOAS — small (PWS≤10,000)	23.5	NR	12.7	5.1	NR
NOAS large (PWS>10,000)	28.8	NR	15.4	6.7	NR
Surface water systems — % > MCL	option <sup>a</sup>				
EPA — proposed rule (all CWS)	9.9	6.0	2.9	0.8	0.3
EPA — final rule (all CWS)	9.8	5.6	3.0	0.8	0.3
NOAS — small (PWS≤10,000)	6.2	NR	1.8	0.0	NR
NAOS — large (PWS>10,000)	7.5	NR	1.3	0.6	NR
Estimate ratios					
EPA — final rule GW:SW	2.8	3.6	4.0	6.6	6.7
NIRS: final rule SW	1.8	2.1	2.3	3.6	3.7
EPA final rule GW: NIRS	1.6	1.7	1.8	1.8	1.8

a. Source: Final Arsenic Rule (U.S. EPA 2001a), Table III.C-8.

## Comparison with California Data

EPA has continued use of the direct proportional and log normal models, using an average of the two models as its "best estimates." The direct proportional method indicates no occurrence for systems serving greater than 500 people for the 40  $\mu$ g/L and 80  $\mu$ g/L MCL options.

To test this assumption, uranium data from California, which has had a uranium MCL of 20 pCi/L (35 µg/L based on conversion factor of 0.67 pCi/µg and rounded down) since 1989, were examined. EPA has also examined uranium data from California and discussed these data

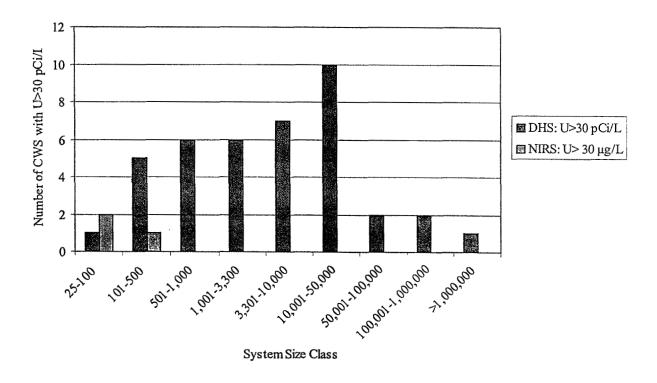
NR = Not reported.

with California Department of Health Services representative (see Appendix C of the Economic Analysis). EPA cites David Spath, Chief, Division of California's DHS as indicating that approximately 125 systems have been out of compliance with the California MCL since it was promulgated and 25 are currently out of compliance. EPA indicated that it did not have information on the populations served by these systems, but that California DHS had described them as "primarily small" and interprets this to mean that these systems primarily serve between 25 and 500 people.

Examination of DHS uranium data for this study revealed that 40 CWS in California have at least one groundwater source with uranium concentrations above 30 pCi/L (using EPA's 1 pCi/μg assumption, this approximates CWS with sources exceeding 30 μg/L). The affected systems were compared with a database that provides population served data for these systems. Exhibit A.2 shows the distribution of these affected systems by population served. Note that only 6 of the 40 systems (12%) serve populations between 25 and 500 people and that only 25 systems (62.5%) serve populations ≤10,000. Fifteen systems (37.5%) serve over 10,000 people. Thus, the California data do not support the assumption that most of the affected systems will serve between 25 and 500 people and further indicates that the direct proportion estimate is inappropriate. The fact that many larger systems are impacted support the observation that many systems in California drill new wells or blend to met the MCL; the larger systems have multiple wells and large service areas where more than one source (including surface water and multiple aquifers) may be available. These non-treatment options may not be available to very small systems serving between 25 and 500 people.

NIRS uranium data for California were also evaluated. Longtin (1990) reported uranium data for 57 systems in 33 California counties. That study showed that 3 systems (one in Kern County and two in Riverside County) had uranium concentrations above 30 µg/L. As shown in Exhibit A.2, these systems served between 25 and 500 people. Thus, the NIRS data are not predictive of uranium occurrence in California when stratified by system size.

Exhibit A.2. Uranium distribution in California CWS



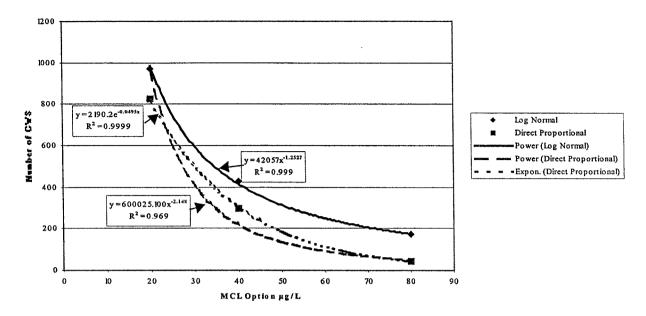
## EPA'S INTERPOLATION METHODOLOGY FOR 30 μG/L MCL

Rather than perform a new CBA for a 30 µg/L MCL, the Agency used interpolation to first compute the number of affected systems and then the associated costs, population affected, risk reduction, and benefits. The Agency fit the data with power functions to describe a relationship between MCL option and the parameter of interest (e.g., number of affected systems). EPA illustrated the relationship for number of systems in Exhibit 7-1 of the Economic Analysis. However, inspection of Exhibit 7-1 of the Economic Analysis indicates that the power equation under-predicts the number of affected systems for the direct proportional occurrence distribution.

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The data were examined to set if another equation would provide a better fit. The results of that evaluation indicated that an exponential equation fits the direct proportional data better than a power equation, while the power equation used by EPA provides the best fit of the log normal data. Exhibit A.3 shows the three curves in question, with equations and  $r^2$  values.

Exhibit A.3. Number of affected CWS vs MCL option



Similar analyses, not shown here, indicate that power equations provide the best fit for interpolating annualized capital and annual operation and maintenance costs for treatment compliance costs.

#### **CONCLUSIONS**

This analysis suggests that the NIRS data likely under-predicts uranium occurrence in groundwater systems, especially those serving populations above 500 people. Thus, the direct proportional model, which shows little occurrence in these larger systems for uranium concentrations above 20  $\mu$ g/L, appears to be inappropriate, and the log normal model provides better occurrence predictions. Comparison with arsenic occurrence studies suggests that the 3:1 ratio of groundwater to surface water occurrence likely increases by a factor of at least two as uranium concentrations increase.

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# APPENDIX B ANALYSIS OF URANIUM MONITORING COSTS

In the NODA, EPA included annual monitoring costs for potential uranium MCLs of 20, 40, and 80 pCi/L for occurrence estimates by the direct proportional method and by the log normal method. In the final rule and Economic Cost Analysis, EPA did not include monitoring costs in the cost-benefit analysis, but did provide monitoring costs for separate uranium monitoring cost for the 30 µg/L MCL. Exhibit B.1 below summarizes these cost estimates. The exhibit also includes interpolated values of monitoring costs for a 30 pCi/L MCL by direct proportional method (linear interpolation) and log normal (log interpolation).

Exhibit B.1 Annual uranium monitoring costs

EDA analysis say		MCL (1 pCi/L = 1 μg/L)	Annual monitoring costs (\$M/yr)	
EPA analysis source				
NODA	Direct proportional	20 pCi/L	5.22	
	Log normal	20 pCi/L	5.48	
	Direct proportional	30 pCi/L	5.06	
	Log normal	30 pCi/L	5.16	
	Direct proportional	40 pCi/L	4.89	
	Log normal	40 pCi/L	5.05	
	Direct proportional	80 pCi/L	4.75	
	Log normal	80 pCi/L	4.86	
Final rule	Average of DP + LN	30 μg/L	0.165	

The final rule costs were presented in terms of present worth costs annualized over 23 years after rule promulgation. The 23 year period includes a 3 year state startup period plus 20 year compliance period. The basis of the NODA costs is unknown; however, they appear to be developed on the same basis of annual treatment costs, which were not discounted. The undiscounted total annual uranium monitoring costs would be about \$194,000 per year, over a 20-year period. Using the NODA data and interpolating between 20 pCi/L and 40 pCi/L, the average annual uranium monitoring costs would be about \$5,160,000 per year for the 30 µg/L MCL. In any case, there is a substantial difference between monitoring costs presented in the NODA and the final rule.

## URANIUM MONITORING REQUIREMENT

Exhibit B.2 provides a summary of the uranium monitoring requirements under the final radionuclides rule. The distribution of CWS by gross alpha and uranium concentrations are those EPA includes in its radionuclides Information Collection Request (ICR). The final rule also includes the monitoring requirements for uranium, including the substitution of gross alpha measurements for uranium when gross alpha is  $\leq$  15 pCi/L. The EPA analysis assumes that one pCi/L of uranium equals one  $\mu$ g/L of uranium. In that analysis, EPA estimates that 558 systems would exceed the 30  $\mu$ g/L uranium MCL, while the final rule indicates that 500 systems would be affected.

Exhibit B.2 Projected final rule uranium sampling requirements

CWS classification by gross alpha and uranium concentrations	Number of CWS	Minimum number of initial U samples	Uranium samples for 9 year cycle
Gross alpha ≤ 3 pCi/L	47,179	0 <sup>a</sup>	1 sample in 9 years <sup>b</sup>
3 pCi/L < gross alpha ≤ 15 pCi/L	4,862	$0^{a}$	1 sample in 6 years <sup>b</sup>
Gross alpha > 15 pCi/L; uranium ≤ 30 μg/L	557	4 samples in 1 year	1 sample in 3 years
Gross alpha > 15 pCi/L; uranium > 30	558	4 samples in 1 year	4 samples per year
μg/L			
Totals	53,156		

a. Final rule allows gross alpha to be substituted for uranium if gross alpha ≤ 15 pCi/L.

#### URANIUM MONITORING COST COMPARISON

The Radionuclides ICR was examined to determine the basis of the uranium monitoring costs and whether the analysis could be replicated. The ICR provides a detailed year analysis of uranium monitoring costs (referred to as Scenario 2A) for a 23 year period beginning November 2000. The monitoring costs are presented in terms of present value and annualized present value. Although not cited in the ICR, EPA appears to have followed the procedures in Section 6 of its Guidelines for Preparing Economic Analyses for discounting costs. Exhibit B.3 summarizes the EPA ICR analysis, which can be easily reproduced if one accepts EPA's occurrence assumptions.

b. Guidance and Implementation Manual unclear as to whether GA measurements can be substituted for these samples.

 $Exhibit \ B.3$  Monitoring cost comparison for 30  $\mu$ g/L uranium MCL

		Guidance	This study
	EPA ICR	manual	best
Monitoring cost parameter	estimate	estimate	estimate
Number of uranium samples over 23 years	27,345	255,370	81,503
Present value of analytical costs, $i = 7\%$ (\$M/y)	1.72	14.1	4.86
Annualized present values (23 year period)			
Annualized analytical cost (\$M/y)	0.150	1.25	0.430
Annualized labor cost (\$M/y)	0.015	0.13	0.043
Total Annualized monitoring cost (\$M/y)	0.165	1.38	0.473
Undiscounted annual monitoring costs (20 year period)			
Number of uranium samples per year	1,367	12,786	4,075
Annual analytical costs (\$M/yr)	0.175	1.63	0.522
Annual labor costs (\$M/yr)	0.019	0.166	0.053
Total annual monitoring costs (\$M/yr)	0.194	1.80	0.575

The EPA ICR uranium monitoring costs appear to represent the minimum costs that utilities may encounter. EPA assumes that about half of the affected systems (U > 30  $\mu$ g/L) will grandfather data, gross alpha data will be substituted for uranium analysis where gross alpha  $\leq$  15 pCi/L, and that after the first sample round of quarterly samples, affected systems will composite quarterly samples and analyze yearly.

The discounted costs in the ICR analysis cover both analytical and labor costs. Exhibit B.3 also includes the undiscounted annual costs (20 year actual sampling period basis). This analysis indicates the total average annual uranium monitoring costs for EPA's ICR would be about \$194,000 per year.

Exhibit B.3 also provides two alternative analyses to compare with EPA's ICR analysis. These include one scenario based on EPA's Draft Implementation Guidance for Radionuclides (EPA 816-D-00-002) and our best estimate of these costs. The Guidance document delineates how states should implement their monitoring programs and specifies sampling frequencies. The Guidance Manual estimate assumes that no data are grandfathered and that after the initial monitoring period, no gross alpha data are substituted for uranium measurements and that systems do not composite samples. This scenario represents the maximum monitoring costs for the assumed CWS distribution. The last column includes a best estimate developed for this study. This estimate is similar to EPA's ICR estimate, in that gross alpha analyses are substituted for uranium analyses when gross alpha ≤ 15 pCi/L and some grandfathering is allowed; however, affected systems do not composite samples and analyses are spread over monitoring periods

uniformly, rather than assume to occur in specific years (e.g., a third of the samples requiring once in 3 years monitoring would be monitored each year rather than all samples monitored every three years).

This comparison indicates that monitoring costs could range from \$194,000 per year (ICR estimate) to \$1,800,000 per year (Guidance Manual estimate), with a best estimate of \$575,000 per year. These monitoring costs represent about 0.4% to 3.5% of the \$49,700,000 per year annualized compliance cost estimate for the 30  $\mu$ g/L MCL in the CBA.

#### APPENDIX C

# USING CBA TO GAIN INSIGHTS WHEN IMPORTANT BENEFITS ARE UNQUANTIFIED OR OMITTED

#### **BACKGROUND**

A challenge in developing and interpreting CBAs arises when an important benefit or cost cannot be readily quantified or expressed in monetary terms. For example, the principal health risk benefit underlying the recent (December 2000) uranium standard is kidney toxicity. The level of renal toxicity risk is highly uncertain and therefore cannot be quantified (i.e., there is no way to estimate a projected number of disease cases avoided). In such a circumstance, benefits cannot be directly compared to costs.

When potentially important benefits (or costs) cannot be directly included in a quantitative CBA, an unsatisfactory option is to ignore the omitted benefits or costs, and base the decision only on those benefits and costs that can be included. This is undesirable because if important benefits are left out, then an MCL will not be set as stringently as it should. Likewise, if important costs are omitted, then the CBA would suggest an MCL that is overly stringent. On the other end of the spectrum, an omitted benefit or cost should not be given undue weight in setting a standard, because the objective is to try to set an MCL at a level that maximizes net social benefits. Therefore, even though an unquantified benefit may be important and should not be overlooked, it should not be used "carte blanche" to set an overly stringent MCL (and vice versa, for an omitted cost).

Given that a potentially significant unquantified (or unmonetized) cost or benefit should neither be ignored or afforded undue weight and influence, the question arises as to how analysts should address the problem. To determine how much weight should be given to considering an unquantified benefit or cost, several informative options can be explored to try to include the omitted (nonmonetized) benefits or costs within the CBA framework in as useful and objective a manner as possible. In some cases, this will simply entail providing a good qualitative discussion of the unquantified outcome so that decision-makers can take it into account along with the numeric CBA findings. If benefits already exceed costs, then a qualitative discussion of

nonmonetized benefits only helps reinforce the obvious outcome (and the same is true if the omitted component is a cost and the monetized net benefits are already negative).

Where the omitted element might alter the net benefit result (e.g., an important benefit is omitted where the monetized CBA components yield a negative net benefit), a "break-even" form of implicit valuation analysis may be useful. This is a semi-quantitative approach in which the analyst back-calculates from the estimated net benefit to determine how large the value of the omitted benefit (or cost) would need to be for the total benefits and costs to be equal (net benefits are zero). For example, if monetized costs exceeded benefits by \$100 million, then a nonmonetized benefit would need to be worth at least \$100 million for the CBA to "break even." It may be quite obvious that the omitted benefit is (or is not) likely to be worth this amount of money. This approach is particularly relevant and applicable to the MCL for uranium (promulgated December 7, 2000, at 65 FR 76707).

## URANIUM AND KIDNEY TOXICITY: INTERPRETING UNQUANTIFIED BENEFITS IN A CBA CONTEXT

In the uranium example, EPA's analysis reveals that modest benefits are expected from reduced risks of cancer, but the monetized value of these benefits are well below the anticipated compliance costs (Exhibits C.1 and C.2). However, the primary health risk of concern is kidney toxicity, because there is some evidence of cellular-level changes in the kidney at elevated levels of long-term uranium exposure. This potential health benefit cannot be quantified as estimated numbers of cases avoided because it is unknown whether the potential for cellular level changes within the kidney are associated with an increased risk of a manifested adverse health effects (i.e., the potential change in kidney cells has not been associated with any increased risk of kidney disease).

Since the level of risk (if any) is not quantifiable, one cannot estimate a number of adverse health effect cases (kidney illnesses) avoided by alternative MCLs. Thus, it also is not possible to directly assign monetary values to these risk reduction benefits. Given the net benefits are negative for the MCL options when considering only the cancer risk reductions, how much weight should be assigned to the potential risks of kidney toxicity? An informative

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Exhibit C.1
Total net benefits: Total benefit minus total cost (millions 1998 \$ per year, cancer benefits only)

MCL option	Total benefits	Total costs	Net benefits
80	\$0.8	\$12.9	\$(12.1)
40	\$1.2	\$33.3	\$(32.1)
30	\$1.4	\$49.7	\$(48.3)
20	\$1.8	\$90.5	\$(88.7)

Costs from EPA Economic Analysis (Dec 2000), Ex 7-7 (U.S. EPA, 2000e).

Costs appear to omit monitoring costs (\$0.2M to \$1.8M/yr at  $30 \mu g/L$ ).

Exhibit C.2
Incremental cost-benefit analysis
(millions 1998 \$ annually, cancer benefits only)

MCL option	Incremental benefits	Incremental costs	Incremental net benefits
base => 80	\$0.8	\$12.9	\$(12.1)
80 => 40	\$0.4	\$20.4	\$(20.0)
40 => 30	\$0.2	\$16.4	\$(16.2)
30 => 20	\$0.4	\$40.8	\$(40.4)

Costs from EPA Economic Analysis (Dec 2000), Ex 7-7 (U.S. EPA, 2000e).

approach can be investigated based on examining the "cost per person exposed." More specifically, since the renal toxicity risks are based on a threshold (i.e., there is a lifetime dose that is considered zero risk, with a margin of safety), the approach can focus specifically on the cost per person for those individuals who would be exposed above the 'safe' level of lifetime exposure without the MCL, but moved below the no risk level by the MCL.

Using standard risk assessment practices for systemic risks, EPA established a drinking water equivalent level (DWEL) concentration of 20 µg/L for uranium. This is the level that EPA states poses no risk of cellular level changes within the kidney to even highly sensitive and highly exposed individuals, with an adequate margin of safety. This "zero risk" level was derived by EPA using standard risk assessment techniques, embodying conservative (precautionary principle) adjustments and assumptions. For example, an uncertainty factor of 100 is applied to the dose-response data, and a exposure is based on 2 L/day of water consumption (which

approximately reflects a 90th percentile of per capita tap water consumption) over a 70 year lifetime.<sup>1</sup>

For any potential MCL option, one can estimate a distribution for the percent of the population expected to exceed the lifetime safe dose. Using census data on the distribution of residential durations, coupled with EPA data on occurrence (estimates of the percent of CWS above each MCL), one can estimate the percent of individuals expected to have exposure durations of varying levels (combining how often people move with the likelihood that they will move into, out of, or return to a CWS with contaminant levels elevated above the given MCL option). The probability distribution of exposure durations can then be coupled with the distribution of tap water consumption derived by EPA, using the reasonable assumption that an individual's daily tap water consumption levels (L/day) are independent of their lifetime exposure duration (years in CWS with water above the MCL).

Given that the DWEL (20 µg/L for Uranium) reflects a 70 year exposure duration for an individual consuming 2 L/day of their CWS tap water, there is virtually no individual who would be expected to consume a total lifetime dose above the zero risk level implied by the oral RfD. Only those individuals that resided for 70 years or more within CWS with elevated uranium and also consumed above the 90th percentile of tap water would exceed the safe lifetime dose, and the joint probability of this occurring in any given individual is virtually zero. At a concentration of 40 µg/L, or twice the uranium DWEL, those who consumed a more typical (near mean) level of 1 L/day of tap water and also resided in uranium-impacted CWS for 70 years or more would be above the lifetime safe dose. At twice the DWEL, those individuals who consume 2 L/day but lived in elevated Uranium CWS for 35 or more years (as well as any person with any combination of water consumption and residence duration scenarios in between) also are above the safe lifetime exposure implied by the oral RfD.

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<sup>1.</sup> EPA recognizes that the compounded effect of the conservative assumptions underlying the DWEL implies that zero risk (or, at worst, de minimus risk) can be achieved with drinking water concentrations above 20  $\mu$ g/L DWEL, stating that there is "not a predictable difference in health effects due to exposures between the DWEL of 20  $\mu$ g/L and a level of 30  $\mu$ g/L" (U.S. EPA, 2000c, p. 76713). EPA adds, "Given that the uncertainty factor of 100 provides a relatively wide margin of safety, the likelihood of any significant effect in the population at 30  $\mu$ g/L is very small. EPA thus believes that the difference in kidney toxicity risk for exposures at 20  $\mu$ g/L versus 30  $\mu$ g/L is insignificant" (U.S. EPA, 2000c, p. 76714). Nonetheless, the illustration developed here uses 20  $\mu$ g/L as the zero risk level for persons consuming 2 L/day for 70 years, and assumes some positive risk exists for lifetime exposures above that level.

Statistical simulations indicate that for any given safe lifetime dose, the following percentages of impacted CWS populations would be above the zero risk lifetime level of exposure: with tap water concentrations at 150% of DWEL (30  $\mu$ g/L for U): 0.24%; 200% of (i.e., twice) the DWEL: 0.52%; and 400% (four times) the DWEL: 1.98%. Using these results, one can determine how many people are moved from above the lifetime safe dose to below the zero risk level by a given MCL increment. For uranium, the estimates are 4271 people from baseline to an 80  $\mu$ g/L MCL, 4844 for the increment from 80  $\mu$ g/L to 40  $\mu$ g/L, 611 for the 40  $\mu$ g/L to 30  $\mu$ g/L increment, and 1317 if the standard is pushed from 30  $\mu$ g/L to 40  $\mu$ g/L.

Exhibit C.3 summarizes the findings, showing the annual and lifetime (70 year) incremental net costs where the quantified benefits include only cancer risk reductions. When these net costs are divided by the number of lifetimes where the risk status has been changed by the MCL options, the incremental cost per person exposed above the lifetime safe dose is derived. As shown in the last column of Exhibit C.3, the implicit valuation outcome for the unquantified benefit was that the "cost per person exposed" (but not necessarily having any adverse health effect) would have to be worth at least \$198,000 for the incremental benefits to be at least as great as the incremental costs of moving from baseline to the 80  $\mu$ g/L MCL option, and jumps to approximately \$2 million per person at the more stringent incremental options headed toward 30  $\mu$ g/L or 20  $\mu$ g/L.

Exhibit C.3
Incremental cost per person exposed to kidney toxicity risk
(monetary results in millions of 1998 \$s per year, population in 000s)

	Incremental population exposed		Incremental net	Cost per person	
MCL option	Total	Above RfD	benefit	exposed above RfD	
base => 80	111.25	4.27	\$(12.1)	\$0.20	
80 => 40	331.75	4.84	\$(20.0)	\$0.29	
40 => 30	218.14	0.61	\$(16.2)	\$1.86	
30 => 20	548.93	1.32	\$(40.4)	\$2.15	

Source: Raucher et al, forthcoming, for Awwa Research Foundation

This type of analysis still leaves room for judgement and interpretation, but at least casts the issue into a framework that is informative. For example, based on the results shown in Exhibit C.3, the unquantifiable benefit now can be considered in the context of, "Is \$200,000 per person (or \$2 million per person) a reasonable investment in public health in this instance?" One

might argue that it seems unlikely that such an expense is warranted. For example, EPA's Cost of Illness Handbook (U.S. EPA, 2001b) and the uranium rule's Economic Analysis (U.S. EPA, 2000e) indicate that \$100,000 is roughly the estimated cost to treat someone with an actual case of cancer, and treating 2 (or 20) known cancer patients seems to be a better public health investment than reducing exposures for 1 person who may not exhibit any discernable kidney function changes or disease. Alternately, the cost of a kidney transplant, including one year of medical care following surgery, now costs less than \$90,000 (University of Maryland Medicine web page www.umm.edu/news/releases/kidcost/html). Should society pay twice this amount to reduce a risk of kidney cellular change in one person?

The analysis in Exhibit C.3 also shows how much the cost per person at risk increases with the more stringent MCL options (because fewer people are at risk, and concurrently the incremental net costs increase). By using this approach, the problem has been placed into a framework that can guide policy deliberations and reveal the consequences of MCL-setting decisions.